REMARKS/ARGUMENTS

Claims 1-28 remain pending. No amendmnet is presently made to any of claims 1-28.

Applicants gratefully note that in response to the previously submitted response, the rejection of claims 10, 11, and 25 has been withdrawn. Claims 6-28 are allowed.

Nevertheless, the Examiner maintains the rejection of claims 1-5 under 35 U.S.C. § 102(b) as being anticipated by Bunnell et al., U.S. Patent 5,703,232. Applicants respectfully traverse.

Claims 1-5 are directed to a process for the preparation of form I of olanzapine. The process comprises the step of crystallizing olanzapine in a solvent mixture which comprises 2-propanol and an effective amount of form I of olanzapine as seeding crystals.

In rendering the anticipation rejection of claims 1-5, the Examiner previously quoted column 1, lines 58-62 of Bunnel, which states: "The present invention provides **a process for preparing anhydrous Form I comprising contacting a lower alcohol solvate with a solvent selected from** the group consisting of ethyl acetate, **2-propanol**, t-butanol, tetrahydrofuran, and toluene." **(Emphasis added.)**

As explained in Applicants' previously submitted response, Bunnell's designation of various anhydrous olanzapine polymorphs is different from the designation used by other references, such as EP-B-733635. Specifically, **Form I discussed in Bunnel is actually form II defined in the present application.** The present application adopts the definition of Form I and Form II, which is generally accepted by other references, such as EP-B-733635. *See* paragraphs 0011, 0012, 0014, and 0016 of the present application as published. As indicated by the information disclosure statement attached with the Office Action dated August 14, 2007, the Examiner has considered EP-B-733635, which was submitted by Applicants previously. As shown at paragraph 0004 of EP-B-733635 and the Table bridging columns 3-4 of Bunnel, the anhydrous Form I of olanzapine discussed in Bunnel is actually Form II of EP-B-733635 and the present application. Likewise, as shown at paragraph 0009 of EP-B-733635 and the Table starting at line 15 of column 4 of Bunnel, the anhydrous Form II of olanzapine discussed in Bunnel is actually Form I of EP-B-733635 and the present application.

In response, the Examiner states that in the absence of the specific x-ray diffraction pattern to describe the invention, i.e., Form I, there is no indication that the present application adopts the

definition of Form I and Form II provided by EP-B-733635. Responsive to the Examiner's argument, Applicants respond as follows.

Claims 1-5 are directed to a process of making Form I, which is known in the art, as disclosed in paragraphs 0011, 0012, 0014, and 0016 of the present application. Form I has been clearly defined in the art, such as EP-B-733635, with X-ray diffraction pattern. Because the present application has referred to the definition of "form I olanzapine" of EP-B-733635, in the specification, there is no need to repeat the definition of Form I provided by EP-B-733635.

As instructed by relevant rules, cases, and guidance, a term recited in a claim, such as "Form I" here, should be construed consistent with the specification. *See* MPEP2111 ("During patent examination, the pending claims must be "given their broadest reasonable interpretation consistent with the specification. . . Indeed, the rules of the PTO require that application claims must 'conform to the invention as set forth in the remainder of the specification and the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description.'" (Emphasis added.) *Quoting Phillips v. AWH Corp.*, 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005) and 37 CFR 1.75(d)(1).)

Here, it is clear from the specification as a whole that the present application adopts the definition of "Form I" provided in most other references, such as EP-B-733635. *See* paragraphs 0011, 0012, 0014, and 0016 as identified above.

Particularly, as stated in paragraph 0034 of the present application, Form II is more stable than From I of olanzapine of the present application.[1] This is consistent with the definition of EP-B-733635 (*see* paragraph 0011 of the present application characterizing Forms I and II of EP-B-733635). In contrast, Bunnell discloses that "Form I" is more stable than "Form II." *See* col. 1, lines 21-33. This further shows that the Bunnell's "Form I" is not the "Form I" recited in the present application.

Therefore, Bunnell fails to disclose any method of making Form I as recited in claims 1-5 of the present, not to mention any specific process as described in claims 1-5 of the present application.

[1] This also demonstrates "the unexpected results" of the present invention, because following the embodiment of the present invention one can obtain a less stable polymorph with substantial purity. For more detail, *see* paragraphs 0034 of the present application.

Nor does Bunnell disclose the use of "an effective amount of form I of olanzapine as seeding crystals" as recited in claims 1-5.

Accordingly, none of claims 1-5 is anticipated by Bunnell under 35 U.S.C. §102(b). Applicants respectfully request that the rejection of claims 1-5 be withdrawn.

Based on the foregoing, Applicants believe that the present application has been placed in condition of allowance. Early and favorable consideration is respectfully requested.

If any additional fees or charges are required at this time, they may be charged to our Patent and Trademark Office Deposit Account No. 03-2412.

Respectfully submitted,
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